Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

VA Hospital Research – Special Considerations

VA HOSPITAL RESEARCH – SPECIAL CONSIDERATIONS

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REQUIREMENTS FOR THE PROTECTION OF
HUMAN SUBJECTS IN RESEARCH WHEN RESEARCH IS VA REGULATED

1. PURPOSE

To assure knowledge and compliance by documenting the policies and procedures to be followed when conducting research involving the Harry S Truman Memorial Veterans Hospital.

2. SCOPE

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board. The Campus IRB does not review VA regulated research.

3. POLICY

The HS IRB has been appointed as the IRB of record for the Harry S Truman Memorial Veterans Hospital. The agreement has been outlined in a Memorandum of Understanding (MOU) signed by both parties. Further, the HS IRB agrees to comply with the federal regulations including 38 CFR 16 and with all applicable regulations as outlined in the VA Handbook 1200.5 "Requirements for Protection of Human Subjects Research in Department of Veterans Affairs (VA) Research. A commercial IRB is prohibited from being used to review VA research projects. VA does not conduct planned emergency research (see 21 CFR 50.24) or classified research involving human subjects.

VA research will be reviewed and monitored in the same manner as all other research under the purview of the HS IRB. It will be expected to comply with the federal regulations and adhere to the HS IRB SOPs as outlined for all research. VA regulations have some additional requirements specific to VA research and these requirements are outlined in these policies and procedures.

For VA research, IRB approval may be granted pending approval of the R&D Committee. Research cannot commence until R&D Committee approval is granted. Therefore, research may not commence until R&D approval has been obtained. The R&D Committee will provide a written approval letter to the investigator with a copy sent to the HS IRB for inclusion in the study files.
Regulations, handbooks and forms referenced within this document can be found on the HSIRB web site http://research.missouri.edu/hsirb/index.htm

4. DEFINITIONS:

a. Administrative Hold. An administrative hold is a voluntary interruption of research enrollments and ongoing research activities by an appropriate facility official, research investigator, or sponsor including the VHA Office of Research and Development (ORD) when ORD is the sponsor.

   (1)The term "administrative hold" does not apply to interruptions of VA research related to concerns regarding:
   (a) The safety, rights, or welfare of human research subjects, research investigators, research staff, or others; or
   (b) The safety, health, or welfare of laboratory animals.

(2) The terms “suspension” and “termination” (defined at subpar. 4aa) apply to research interruptions related to the concerns described at subparagraph 4a(1)(a) and 4a(1)(b).
(3) An administrative hold must not be used to avoid reporting deficiencies or circumstances otherwise covered by this Handbook, related Handbooks, or other Federal requirements governing research.

b. Adverse Event. An adverse event (AE) in human subjects research is any untoward physical or psychological occurrence in a human subject participating in research. NOTE: AEs are further discussed in VHA Handbooks 1058.01, Research Compliance Reporting Requirements, and 1004.08, Disclosure of Adverse Events to Patients.

c. Assurance. An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule. NOTE: Assurances are further discussed in VHA Handbook 1058.03, Assurance for Protection for Human Subjects in Research.

d. Collaborative Research. Collaborative research involves investigators from more than one institution. Collaborative research may include VA and non-VA institutions but does not include research conducted under a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical company or other non-Federal partners.

e. Continuing Noncompliance. Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human subjects research. NOTE: Continuing noncompliance is further discussed in VHA Handbook 1058.01.

f. Investigator. An investigator is an individual who conducts research, including the principal investigator, co-investigators, sub-investigators, and local site investigators (see paragraph 29). NOTE: The responsibilities of VA investigators are further discussed in VHA Handbook 1200.01.

g. Legally Authorized Representative. A legally authorized representative (LAR) is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. NOTE: An individual who is qualified as a LAR to provide informed consent on behalf of a prospective research subject may not always qualify as a personal representative for purposes of consent to use or disclose a subject’s protected health information (PHI) (i.e., signing a Health Insurance Portability and Accountability Act (HIPAA) authorization). Therefore, in circumstances involving authorization for use or disclosure of a human subject’s PHI, the investigator must ensure the LAR meets the requirements of a personal representative under HIPAA and the Privacy Act of 1974 (legal guardian or power of attorney) prior to the LAR’s signing a HIPAA authorization (see VHA Handbook 1605.1, Privacy and Release of Information).

h. Multi-site Research. Multi-site research involves more than one research site. Multi- site research may include VA and non-VA institutions, and may include both collaborative research and research conducted under a CRADA with a pharmaceutical company or other non- Federal entity. NOTE: See the definition for Collaborative Research.

i. Nonprofit Research and Education Corporations. VA-affiliated nonprofit research and education corporations (NPC) are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee and education approved by the facility Education Committee is considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site (see VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations authorized by 38 U.S.C. Sections 7361-7366).

j. Research. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this Handbook. NOTE: Research activities are further discussed in VHA Handbook 1058.05.

k. Research Records. Research records include, but are not limited to, IRB and R&D Committee records, records of all observations, subject recruitment activities, other data relevant to the investigation, progress notes, research study forms, surveys, questionnaires, and other documentation regarding the study (see VHA Handbook 1907.01, Health Information and Health Records).

l. Research and Development Committee. The R&D Committee is a committee responsible, through the Chief of Staff (COS) to the VA facility Director, for oversight of the facility's research program and for maintenance of high standards throughout that program (see VHA Handbook 1200.01).

m. Research Protocol. A research protocol details the aims and objectives of a research study, scientific rationale, the methods used to carry out the research, and how data will be analyzed. For human subjects research it also entails how subjects will be accessed/recruited, any foreseeable risks, and how these risks will be mitigated. NOTE: The protocol for social or behavioral research is sometimes referred to as the "Research Plan" or "Research Purpose and Methodology."

n. Serious Adverse Event. A serious adverse event (SAE) is an AE in human subjects research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect. An AE is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent such an outcome. NOTE: SAE's are also discussed at 21 CFR 312.32(a) and in VHA Handbook 1058.01; disclosure of adverse events to patients is discussed in VHA Handbook 1004.08.

o. Serious Noncompliance. Serious noncompliance is a failure to adhere to the laws, regulations, or policies governing human subjects research that may reasonably be regarded as:

(1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or

(2) Substantively compromising the effectiveness of a facility's human subjects research protection or human subjects research oversight programs. NOTE: Serious noncompliance is further discussed in VHA Handbook 1058.01.

p. Suspension or Termination of Research. Refers to the suspension or termination of research as it relates to VA research and are described as follows:

(1) Suspension refers to a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.
(2) Termination refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.
(3) Suspension and termination also apply to interruptions related to concerns regarding:
(a) The safety, rights, or welfare of human subjects, research investigators, research staff, or others; or
(b) The safety, health, or welfare of laboratory animals.
(4) Suspension and termination does not include:
(a) Interruptions in research resulting solely from the expiration of a project approval period.
(b) Administrative holds or other actions initiated voluntarily by an appropriate facility official, research investigator, or sponsor for reasons other than those described in subparagraph. 4aa(3).

q. Unanticipated or Unexpected. The terms unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

r. VA Research. VA research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval. NOTE: VA research is discussed in VHA Handbook 1200.01 and VHA Handbook 1200.2, Research Business Operations.

5. Responsibilities of the Institutional Official.
The VA IO's responsibilities for the facility's HRPP include, but are not limited to:

(1) Ensuring that a procedure is in place to review and approve recruiting documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff (see ORD guidance at http://www.research.va.gov/resources/policies/default.cfm).

a. May only be posted if federally funded and
b. Approved by the VA research office

(2) When the facility engages the services of another entity's IRB as its IRB of Record, the IO is responsible for:

(a) Establishing and signing a memorandum of understanding (MOU) or Authorizing Agreement with other VA facilities or external organization(s) providing IRB services (see VHA Handbook 1058.03 and MOU Checklist: http://www.va.gov/ORO/orochecklists.asp); and

(b) Ensuring that at least two VA-compensated (minimum 1/8th full-time employee equivalent) staff from the facility are appointed as voting members to each IRB of Record. A small VA facility with fewer than ten active protocols is only required to appoint one voting member and one alternate voting member to ensure consistent representation. NOTE: At least one VA voting member of the IRB must be in attendance when their facility's research is discussed at a convened meeting.

6. IRB MEMBERSHIP:

a. Retired VA employees who are receiving VA retirement benefits are considered to be affiliated when they are members of a VA IRB. NOTE: Veterans who receive their care at the facility, but have never been employed by VA, would not be considered affiliated.

b. VA facility research office staff including, but not limited to, the ACOS for R&D, the AO for R&D, and IRB administrative staff may not serve as voting members of the facility's IRB. They may serve as ex officio, non-voting members; however, they and the IRB must be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts. NOTE: Ex officio members are for purposes of this Handbook not allowed to be voting members of the IRB.

c. Research Compliance Officers (RCOs) may act as consultants to the facility's IRB, but may not serve as voting or non-voting members of the IRB. RCOs may attend IRB meetings when requested by the IRB or as specified by the IRB's standard operating procedures (SOPs). RCO's must be aware of and manage any potential, actual, apparent, or perceived conflicts of interest that arise because of their role. NOTE: RCOs are further discussed in VHA Handbook 1058.01.

d. The Privacy Officer (PO) and the Information Security Officer (ISO) serve in an advisory capacity to the facility's IRB as either non-voting members or as consultants (see paragraph 22 for specific roles and responsibilities).

e. Facility Directors, their administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative Staff may observe IRB meetings, but may not serve as voting or non-voting members of the facility's IRB.

f. The IO appoints IRB voting members in writing. Appointment procedures for ex officio, non-voting members are made according to local SOPs and any other applicable VA requirements. Voting members of VA IRBs and VA representatives to external IRB(s) of

Record are appointed for a period of up to 3 years. They may be re-appointed to new terms of up to 3 years without a break in service at the end of each term. NOTE: There are not a maximum number of terms for IRB members as long as the composition of the IRB meets all requirements.

7. IRB FUNCTIONS AND OPERATIONS:

The IRB:

(1) reports findings and actions to the, R&D Committee, investigator;

(2) IRB minutes are submitted to the R&D Committee in accordance with local SOPs. When an affiliate IRB is the IRB of Record, the affiliate will:

(a) Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.

8. CRITERIA FOR IRB APPROVAL:

1. VA specific criteria to be met:

(a) Privacy and confidentiality provisions must take into consideration the requirements of Standards for Privacy of Individually-Identifiable Health Information (HIPAA Privacy Rule), 45 CFR Parts 160 and 164, and other laws regarding protection and use of Veterans' and others information, including the Privacy Act of 1974, 5 U.S.C. 552a; VA Claims Confidentiality Statute, 38 U.S.C. 5701; Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Infection with Human Immunodeficiency Virus (HIV), and Sickle Cell Anemia Medical Records, 38 U.S.C. 7332; and Confidentiality of Healthcare Quality Assurance Review Records, 38 U.S.C. 5705 (see VHA Handbook 1605.1);

(b) Relevance of the research to the mission of VA and the Veteran population that it serves must be considered by the IRB. If non-Veterans will be included, the protocol and related materials must justify the inclusion of non-Veterans; and

9. REVIEW BY INSTITUTION:

a. Officials of the institution may not approve human subjects research if it has not been approved by the IRB.

b. An IRB-approved research activity may be disapproved by the IO, the R&D Committee, or ORD. If a research activity is disapproved by the IRB, or modifications to the research are required by the IRB, the disapproval or need for modification cannot be overruled by any other authority (e.g., IO or R&D Committee).

c. The R&D Committee must provide the final approval before the research can be initiated in accordance with VHA Handbook 1200.01.

d. Continuing review and re-approval of research must occur on or before the date when IRB approval expires. If approval expires, the investigator must:
(1) Stop all research activities including, but not limited to, enrollment of new subjects, analyses of individually identifiable data, and research interventions or interactions with currently participating subjects, except where stopping such interventions or interactions could be harmful to those subjects; and
(2) Immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping specified study interventions or interactions. The IRB Chair must determine within 2 business days whether or not such interventions or interactions may continue.

e. Initiation of Research Projects. IRB approval is for a specified time period based on the degree of risk of the study, not to exceed 1 year. The IRB determines the expiration date based upon its date of review and communicates that date to the investigator in the written approval letter. The investigator must not initiate the IRB approved research protocol until all applicable requirements in VHA Handbook 1200.01 have also been met including obtaining R&D Committee approval.

The ACOS for R&D is responsible for:
a. Notifying the investigator when a research project can be initiated. This notification occurs only after the research project has been approved by all applicable R&D Committee subcommittees, and after the R&D subcommittees' notifications of approvals have been approved by the R&D Committee. The ACOS for R&D is responsible for notifying the investigator of approval after continuing review by the R&D Committee and subcommittees.

10. Reporting Local Deaths, Local Serious Adverse Events (SAE's), and Serious Problems

a. **Local Research Deaths.** VA personnel, including WOC and IPA appointees, must ensure oral notification of the Institutional Review Board (IRB) immediately (within the day) upon becoming aware of any local research death that is both unanticipated and related to the research. If notification is not taking place by the study team the PI must be notified immediately.

(1) The IRB must alert the RCO by e-mail or telephone immediately after receiving such notification and provide relevant information as requested. The VA facility Director and the ACOS/R&D will receive concurrent notification from the RCO.

(2) VA personnel, including WOC and IPA appointees, must submit the *Onsite Death Form* to the IRB within 5 business days of becoming aware of the death.

(3) Within 5 business days after receiving written notification of the death, the IRB Chair or a qualified IRB member-reviewer must determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects.

(4) The IRB must review the death and the determination of the IRB Chair or qualified IRB member-reviewer at its next convened meeting and must determine and document that:

(a) The death was both unanticipated and related to the research; or

(b) There is insufficient information to determine whether the death was both unanticipated and related to the research; or

(c) The death was not unanticipated and/or the death was not related to the research.

(5) Regardless of the determination under paragraph 6.a(4), the convened IRB must also determine and document whether any protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.

(6) The IRB must notify the RCO of its determinations under paragraphs 6.a(4) and 6.a(5) within 5 business days of the determinations.

(7) The VA facility Director must report the determinations to ORO within 5 business days after receiving the IRB's notification.

b. **Local SAEs.** VA personnel, including WOC and IPA appointees, must ensure submission of an *Event Form* to the IRB within 5 business days after becoming aware of any local SAE that is both unanticipated and related to the research.

c. **Serious Problems.** VA personnel, including WOC and IPA appointees, must submit and *Event Form* to the IRB within 5 business days after becoming aware of any serious problem that is both unanticipated and related to the research. ***NOTE:*** *For examples, see the ORO SharePoint/Web sites* at *http://www.va.gov/oro/*.

d. **IRB Review of SAEs and Serious Problems.** Within 5 business days after receiving submission of an SAE or serious problem under paragraph 6.b. or 6.c., the IRB Chair or a qualified IRB member-reviewer must determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects.

(1) The IRB must review the incident and the determination of the IRB Chair or qualified IRB member-reviewer at its next convened meeting and must determine and document that:

(a) The incident was serious and unanticipated and related to the research; or

(b) There is insufficient information to determine whether the incident was serious and unanticipated and related to the research; or

(c) The incident was not serious, and/or the incident was not unanticipated, and/or the incident was not related to the research.

(2) Regardless of the determination under paragraph 6.d(1), the convened IRB must also determine and document whether any protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not

investigators must notify or solicit renewed/revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.

(3) The IRB must notify the RCOin writing within 5 business days after its convened meeting if:

(a) Actions were taken to eliminate apparent immediate hazards to subjects; or

(b) The IRB determined that the incident was serious and unanticipated and related to the research, or there was insufficient information to make the determination; or

(c) Protocol or informed consent modifications were warranted.

(4) The VA facility Director must report the situation to ORO within 5 business days after receiving the IRB's notification.

e. **Other AEs, SAEs, and Problems.** The IRB must be notified of, and review, other AEs, SAEs, and unanticipated problems involving risks to subjects or others (i.e., not covered by paragraphs 6.a. through 6.c.) in accordance with local SOPs.

f. **Apparent Serious or Continuing Noncompliance.** VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing by submission of an *Event Form*, within 5 business days after becoming aware of any apparent serious or continuing noncompliance with IRB or other human research protection requirements.

***NOTE**: HIPAA Privacy Rule deficiencies, including uses and disclosures of PHI for research without legal authority (e.g., without a valid authorization or waiver of authorization), are to be reported in accordance with paragraph 6.f. Such deficiencies should also be reported to the facility Privacy Officer (PO).*

***NOTE:** For additional examples of apparent serious noncompliance, see the ORO SharePoint/Web sites at http://www.va.gov/oro/.*

(1) The convened IRB must review any such notifications at the earliest practicable opportunity, not to exceed 30 business days after the notification. The IRB Chair may take interim action as needed to eliminate apparent immediate hazards to subjects.

(2) The convened IRB must determine and document whether or not serious or continuing noncompliance actually occurred.

(3) If the IRB determines that serious or continuing noncompliance occurred:

(a) A documented IRB determination is also required as to whether remedial actions are needed to ensure present and/or future compliance.

(b) IRB must notify the RCO within 5 business days after making its determinations.

(c) The VA facility Director must report the determination to ORO within 5 business days after receiving the IRB's notifications.

(d) If the apparent serious or continuing noncompliance was identified by an RCO audit, the IRB must notify the RCO within 5 business days after its determinations under paragraphs 6.f.(2) and 6.f.(3)(a), regardless of outcome.

g. **Other Apparent Noncompliance.** The IRB must be notified of, and review, other apparent noncompliance (not covered by paragraph 6.f) in accordance with local SOPs.

h. **Suspensions and Terminations of Research by the VA Facility.** VA facility officials and research review committees must notify the RCO within 5 business days of suspending or terminating any VA human research study. The VA facility Director must report the suspension/termination to ORO within 5 business days after receiving the notification.

i. **External Suspensions/Terminations of Research.** VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing, within 5 business days after becoming aware of any suspension or termination of VA research by, or at the direction of, any entity external to the facility.

(1) The convened IRB must review the suspension/termination at the earliest practicable opportunity, not to exceed 30 business days after notification, to determine whether it:

(a) Resulted from a local adverse event(s), local noncompliance, or other local issue(s); or

(b) Requires local action (in addition to the suspension/termination) to ensure the safety, rights, or welfare of local human research subjects, personnel, or others or the effectiveness of the local HRPP.

(2) If the IRB determines that either 6.i.(1)(a) or 6.i.(1)(b) applies,

(a) The IRB must notify the RCO within 5 business days after the determination;

(b) The VA facility Director must report the suspension/termination to ORO within 5 business days after receiving the IRB's notification.

11. COLLABORATIVE RESEARCH: This section addresses collaborations between VA and non-VA investigators. Collaboration is encouraged when VA investigators have a substantive role in the design, conduct, and/or analysis of the research. VA may also serve as a Coordinating Center for collaborative studies. NOTE: For purposes of this Handbook, collaborative studies do not include studies conducted under a CRADA with pharmaceutical companies or other for-profit entities.

(1) Each institution engaged in the collaborative research must use the informed consent document and HIPAA authorization required by their respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subject at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed at VA and which will be performed at other institutions.

(a) The VA informed consent document must clearly state when procedures mentioned at other institutions are part of the VA's portion of the study.

(b) The informed consent document and HIPAA authorization must be consistent and include information describing the following:

1. PHI to be collected and/or used by the VA research team;

2. PHI to be disclosed to the other institutions; and

3. Purpose for which the PHI may be used.

(c) Waivers. PHI obtained in research for which the IRB of Record has waived the requirements to obtain a HIPAA authorization and a signed informed consent document may not be disclosed outside VA unless the VA facility Privacy Officer ensures and documents VA's authority to disclose the PHI to another institution. A waiver of HIPAA authorization is not sufficient to fulfill the requirements of other applicable privacy regulations such as the Privacy Act of 1974 (5 U.S.C. 552a).

(2) Research Data. The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, and how the data are to be transmitted. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.

(3) Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1.

(4) All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, VA Handbook 6500, and VHA Handbook 1605.1.

(5) Written agreements. Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a CRADA or a Data Use Agreement (DUA)) that addresses such issues as the responsibilities of each party, the ownership of the data, and the reuse of the data for other research. NOTE: Any reuse must be consistent with the protocol, the informed consent document, and the HIPAA authorization.

12. IRB RECORDS:

a. All records must be accessible for inspection and copying by authorized representatives of VA, ORO, OHRP, FDA, and other authorized entities at reasonable times and in a reasonable manner. Records should be disposed in accordance with VHA RCS 10-1.

b. IRB records are the property and the responsibility of the local research office. The local VA facility must designate where the records will be maintained or stored. NOTE: Records of an affiliate IRB are addressed in the MOU (see paragraph 5.d.(2)(a) and VHA Handbook 1058.03). The MOU must ensure that all applicable federal and VA regulations are met.

13. Informed Consent

(1) If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing (e.g., by use of a delegation letter) to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects, and about the ethical basis of the informed consent process and protocol.

(2) If the investigator contracts with a firm, e.g., a survey research firm, to obtain consent from subjects, collect private individually identifiable information from human subjects, or are involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the PO must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.

14. REQUIREMENTS FOR INFORMED CONSENT:

a. Additional Elements Required by VA. The following additional elements of informed consent are required for VA research:

(1) Any payments the subject is to receive for participating in the study;

(2) Any real or apparent conflict of interest by investigators where the research will be performed; and

(3) A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations (see paragraph 25).

b. Additional Elements of Informed Consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or becomes pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject;

(5) A statement that any significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects to be entered in the study; and

(7) When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. NOTE: Some Veterans are required to pay copayments for medical care and services specifically related to their medical care provided by VA. These co-payment requirements will continue to apply to medical care and services that are not part of the research procedures or interventions.

15. DOCUMENTATION OF INFORMED CONSENT:

a. The IRB may waive the requirement for the investigator to obtain a signed consent document for some or all subjects.

b. VA-specific Requirements.

(1) The consent form must be the most recent IRB-approved consent form that includes all the required elements and, as appropriate, additional elements. The IRB approval must be documented on the consent form indicating the date of approval.

(2) The informed consent document must be signed and dated by:

(a) The subject or the subject's LAR; and

(b) The person obtaining the informed consent. However, the IRB may waive this requirement for the signature of the person obtaining consent (even where the signature of the subject or the LAR continues to be required) where there is no physical contact with the subject (e.g., where the only contact with the subject is by telephone or mail).

c. Consent may be obtained electronically so long as the informed consent process meets all requirements in paragraph 16 of this Handbook and VA requirements; and:

(1) Authentication controls on electronic consent provide reasonable assurance that such consent is rendered by the proper individual; and

(2) The subject dates the consent as is typical or that the software provides the current date when signed.

d. Photography, Video and/or Audio Recording for Research Purposes. The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio recordings will be used for the research, and whether the photographs, video, and/or audio recordings will be disclosed outside VA.

(1) An informed consent to take a photograph, video and/or audio recording cannot be waived by the IRB.

(2) The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside VA. A HIPAA authorization is needed to make such disclosures.

16. Flagged Health Record Contents.

If IRB determines and documents that the patient health record must be electronically flagged in Computerized Patient Record System (CPRS) as participating in a research study then, the health record must:
(1) Identify the investigator, as well as contact information for a member of the research team that would be available at all times. NOTE: The research team must have an appropriate member available (on-call) at all times.
(2) Contain information on the research study or identify where this information is available.

The IRB may determine that the patient health record must be flagged if the subject's participation in the study involves:

(a) Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
(b) Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive; or
(c) In other situations, the IRB determines if flagging is necessary.

17. RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES AS SUBJECTS:

a. Research that involves provision of in vitro fertilization services cannot be conducted by VA investigators while on official duty, or at VA facilities, or at VA-approved off-site facilities. NOTE: Prospective and retrospective studies that enroll or include pregnant subjects who conceived through in vitro fertilization or other artificial reproductive technologies are permitted.

b. Research in which the focus is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue), cannot be conducted by VA investigators while on official duty, at VA facilities, or at VA-approved off-site facilities. Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding.

c. VA investigators cannot conduct interventions in research that enroll neonates while on official duty, or at VA facilities, or at VA-approved off-site facilities. Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted.

d. Women who are known to be pregnant and/or their fetuses may be involved in research if all of the requirements of 45 CFR 46.204 are met including informed consent requirements and the following ethical and scientific criteria:

(1) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(2) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or fetus. If there is no such prospect of benefit, then the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

(3) Any risk is the least possible for achieving the objectives of the research; and

(4) The VA medical facility Director certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research (see guidance at http://www.research.va.gov/resources/policies/default.cfm).

18. RESEARCH INVOLVING PRISONERS AS SUBJECTS:

a. Research involving prisoners cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO. NOTE: Refer to the ORD Web site at http://www.research.va.gov/resources/policies/default.cfm for details on the procedures for waiver applications.

b. If such a waiver is granted, the research must comply with the requirements of 45 CFR 46.301 - 46.306. NOTE: A link to these requirements is provided on the ORD Web site at: http://www.research.va.gov/resources/policies/default.cfm.

19. RESEARCH INVOLVING CHILDREN AS RESEARCH SUBJECTS:

a. VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to Veterans. Therefore, research involving children must be reviewed carefully by the IRB for its relevance to VA and must not be greater than minimal risk. The VA medical facility Director must approve participation in the proposed research that includes children (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).

NOTE: For purposes of this Handbook, research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. If the biological specimens or data were previously collected, they must have been collected under applicable policies and ethical guidelines.

b. The IRB must have the appropriate expertise to evaluate any VA research involving children and must comply with the requirements of 45 CFR 46.401 - 46.404 and 46.408. NOTE: A link to these requirements is provided on the ORD Web site at: http://www.research.va.gov/resources/policies/default.cfm.

20. SUBJECTS LACKING DECISION-MAKING CAPACITY:

a. Criteria for Enrollment. Individuals who lack decision-making capacity may be enrolled in VA research where:

(1) The IRB determines that the proposed research entails: (a) No greater than minimal risk to the subject; or
(2) Presents a greater probability of direct benefit to the subject than harm to the subject; or

(3) Greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

(A) In addition to satisfying the conditions above, the IRB determines that:

(1) The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects' lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke); or

(2) The subject of the research is not directly related to the subjects' lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects (e.g., transmission of methicillin-resistant staphylococcus aureus infections in a nursing home where both individuals with and without decision-making capacity are affected).

b. Determination of Capacity. When planning to enter subjects with impaired decision- making capacity, investigators must address in the protocol how they will determine when surrogate consent (i.e., a LAR) will be required. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity. However, the IRB must review and approve the plan to ensure that it is appropriate given the population and setting of the research. NOTE: Individuals ruled incompetent by a court of law are considered to lack decision-making capacity.

c. Surrogate consent. When the potential subject is determined to lack decision-making capacity, investigators must obtain consent from the LAR of the subject (i.e., surrogate consent). NOTE: Investigators and IRBs have a responsibility to consult with the Office of General Counsel (OGC) regarding state or local requirements for surrogate consent for research that may supersede VA requirements.

d. Authorized Person. The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority in accordance with VA regulations at 38 CFR 17.32(e), (g)(3). NOTE: Consent for research is required in addition to the consent that is obtained for the patient's non-research related treatments and procedures.

(1) Health care agent (i.e., an individual named by the subject in a Durable Power of Attorney for Health Care);

(2) Legal guardian or special guardian;

(3) Next of kin: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or

(4) Close friend.

NOTE: The persons authorized to consent on behalf of persons who lack decision-making capacity for participation in the research may not necessarily be the same as the persons authorized to provide permission for the use and disclosure of information on a HIPAA authorization on behalf of persons who lack decision-making capacity (see VHA Handbook 1605.1).

e. Dissent or Assent. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

f. Responsibilities of LARs. LARs are acting on behalf of the potential subjects, therefore:

(1) LARs must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision.

(2) If the potential subjects' wishes cannot be determined, the LARs must be told they are responsible for determining what is in the subjects' best interest.

21. CERTIFICATES OF CONFIDENTIALITY:

a. When VA conducts a study that is protected by a Certificate of Confidentiality, the following health record documentation provisions apply:

(1) For studies that do not involve a medical intervention (e.g., observational studies, including interview and questionnaire studies), no annotation may be made in the health record.

(2) For studies that involve a medical intervention, a progress note entry should indicate that an individual has been enrolled in a research study, any details that would affect the subject's clinical care, and the name and contact information for the investigator conducting the study. Subjects' informed consent forms and HIPAA authorization documents are not to be included in the health record.

b. Investigators should work with the research office in their facility to assure that when Veterans are enrolled in a study protected by a Certificate of Confidentiality, they are not simultaneously enrolled in other interventional studies unless it is absolutely clear that this enrollment does not raise safety issues.

22. PRIVACY OFFICER AND INFORMATION SECURITY OFFICER DUTIES: The PO and the ISO serve in an advisory capacity to the IRB as either non-voting members or as consultants. The facility PO and ISO are responsible for:

a. Ensuring that the proposed research complies with all applicable local, VA, and other Federal requirements for privacy and confidentiality, and for information security, by identifying and addressing potential concerns about proposed research studies.

b. Reviewing the proposed study protocol, study specific privacy and security information, and any other relevant materials submitted with the IRB application.

c. Identifying deficiencies in the provisions for privacy and confidentiality or information security, respectively, of the proposed research, and making recommendations to the investigator and/or the IRB of options available to correct the deficiencies.

d. Following up with the investigator and/or the IRB, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality and information security requirements, respectively, before the investigator initiates the study.

e. A final review is required only after the IRB has approved the study to ensure no further changes impact the privacy and security requirements of this study.

NOTE: If a study includes information covered under 38 U.S.C. 7332 that will be disclosed outside of VA, the study must include written assurance from the VA researcher, e.g. within the protocol, that the purpose of the data is to conduct scientific research and that no personnel involved in the study will identify, directly or indirectly, any individual patient or subject in any report of such research, e.g. manuscript or publication.

23. HIPAA AUTHORIZATION:

(1) VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used to document the authorization. The authorization may not be embedded in the consent form;

(2) The PO must review the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol (see VHA Handbook 1605.1);

a. Activities Preparatory to Research. VA investigators may use individually-identifiable health information to prepare a research protocol prior to submission of the protocol to the IRB for approval without obtaining a HIPAA authorization or waiver of authorization.

(1) VA investigators must not arbitrarily review PHI based on their employee access to PHI until the investigator documents the following required information as "Preparatory to Research" in a designated file that is readily accessible for those required to audit such information (e.g., Health Information Manager or PO):

(a) Access to PHI is only to prepare a protocol;

(b) No PHI will be removed from the covered entity (i.e., VHA); and

(c) Access to PHI is necessary for preparation of the research protocol.

(2) Non-VA researchers may not obtain VA information for preparatory to research activities without appropriate VA approvals (see VHA Handbook 1605.1).

Both IRB and VA research office must be obtained.

(3) During the preparatory to research activities the VA investigator:

(a) Must only record aggregate data. The aggregate data may only be used for background information to justify the research or to show that there are adequate numbers of potential subjects to allow the investigator to meet enrollment requirements for the research study;

(b) Must not record any individually identifiable health information; and

(c) Must not use any individually identifiable information to recruit research subjects.

NOTE: Preparatory activities can include reviewing database output (computer file or printout) containing identifiable health information generated by the database owner, if the investigator returns the database output to the database owner when finished aggregating the information.

(4) Contacting potential research subjects and conducting pilot or feasibility studies are not considered activities preparatory to research.

(5) Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.

24. PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS:

a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. The investigator must justify including non-Veterans and the IRB must review the justification and provide specific approval for recruitment of non- Veterans.

(1) Outpatient Care for Research Purposes. Any person who is a bona fide volunteer may be furnished outpatient treatment when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (38 CFR 17.92).

(2) Hospital Care for Research Purposes. Any person who is a bona fide volunteer may be admitted to a VA hospital when the treatment to be rendered is part of an approved VA research study and there are insufficient Veteran patients suitable for the study (38 CFR 17.45).

b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.

c. In addition to the non-Veterans referenced above, active duty military personnel may be entered into VA research conducted jointly by VA and DoD or within DoD facilities.

d. All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research.

e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

f. Investigators must follow VHA Handbook 1605.04, Notice of Privacy Practices, to provide notice of privacy practices and acknowledgement for any non-Veteran enrolled in the approved protocol.

25. TREATMENT OF RESEARCH-RELATED INJURIES:

a. VA medical facilities, including joint VA-DoD federal health care centers, must provide necessary medical treatment (i.e., not just emergency treatment) to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees (38 CFR 17.85). This requirement does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures; or

(2) Research conducted for VA under a contract with an individual or a non-VA institution. b. Care for VA research subjects under this paragraph must be provided in VA medical facilities, except in the following situations:

(a) If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility Directors shall contract for the needed care;

(b) If inpatient care must be provided to a non-Veteran under this paragraph, VA medical facility Directors may contract for such care; or

(c) If a research subject needs treatment in a medical emergency for a condition covered by this paragraph, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

26. INTERNATIONAL RESEARCH:

a. VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. NOTE: For the purposes of this Handbook, research conducted at U.S. military bases, ships, or embassies is not considered international research.

(1) Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the U.S. or Puerto Rico and accessed via a secure connection is not considered international research.

(2) International research includes multi-site trials involving non-U.S. sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the Investigational New Drug (IND), or the VA manages the data collection and the data analyses.

(3) International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator).

b. Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html). NOTE: The VA medical facility Director must approve participation in the proposed international research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).

c. All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO.

d. All international sites should hold an international Federal Wide Assurance (FWA).

e. The research should be approved by the IRB or Research Ethics Board of the participating site(s) that are listed on the international FWA.

27. STUDENT AND OTHER TRAINEE RESEARCH:

a. Trainees (e.g., students, residents, or fellows of any profession) may serve as participants, but not PIs within a VA facility, use VA human subjects data, or use human biological specimens that have been collected within VA for clinical, administrative, or research purposes only when: and

(1) The study has been approved by the local VA medical facility and IRB, if appropriate;

(2) Either they are:
(a) Enrolled in an institution with an educational affiliation agreement with that VA facility; or (b) Directly appointed to a VA training program that has no external institutional sponsorship (e.g. VA Advanced Fellowship). NOTE: A waiver may be obtained from the CRADO under special circumstances.

b. A VA investigator sufficiently experienced in the area of the trainee's research interest must serve as PI and is responsible for oversight of the research and the trainee/student. The PI is responsible for ensuring the trainee/student complies with all applicable local, VA and other federal requirements including those related to research, information security, and privacy.

(1) If the trainee does not complete all aspects of the research prior to leaving VA, the VA investigator must ensure the protocol is completed or terminated in an orderly fashion, and in accordance with all applicable local, VA, and other federal requirements.
(2) When the trainee leaves VA, the VA investigator is responsible for ensuring that all research records are retained by VA.

28. VA INVESTIGATOR RESPONSIBILITIES: The investigator must give first priority to the protection of research subjects, uphold professional and ethical standards and practices, and adhere to all applicable VA and other federal requirements, including the local VA facility's policies and procedures, regarding the conduct of research and the protection of human subjects. The investigator must hold a current VA appointment to conduct VA research.

a. Qualifications to Conduct Human Subjects Research. VA investigators must have the appropriate training, education, expertise, and credentials to conduct the research according to the research protocol.

(1) PIs must ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the study.

(2) Investigators and their staff conducting human subjects research must be credentialed and privileged as required by current local and VA requirements (see VHA Handbook 1100.19 and VHA Directive 2012-030, Credentialing of Health Care Professionals, or successor policy). Investigators and their research staff may only perform those activities in a research study for which they have the relevant credentials and privileges.

(3) All individuals involved in conducting VA human subjects research are required to complete training in ethical principles on which human subjects research is to be conducted. Specific requirements regarding the type and frequency of training are found on ORD's Web site at: http://www.research.va.gov/pride/training/options.cfm. All other applicable VA and VHA training requirements at the local and national level must be met (e.g., privacy and information security training).

b. Research Protocol. The investigator must develop and submit a research protocol that is scientifically valid, describes the research objectives, background and methodology, provides for fair and equitable recruitment and selection of subjects, minimizes risks to subjects and others,

and describes a data and safety monitoring plan consistent with the nature of the study. The research must be relevant to the health or welfare of the Veteran population. When relevant, the protocol must include the following safety measures:

(1) The type of safety information to be collected including AEs;
(2) Frequency of safety data collection;
(3) Frequency or periodicity of review of cumulative safety data;
(4) Statistical tests for analyzing the safety data to determine if harm is occurring; and
(5) Conditions that trigger an immediate suspension of the research, if applicable.

c. Approvals. The investigator must submit the protocol for initial review and obtain written approvals from the IRB, other applicable committees, and from the R&D Committee. In addition, the investigator must receive written notice from the ACOS/R&D that the research may commence before initiating the research.

d. Initial Contact. During the recruitment process, members of the research team must make initial contact with potential subjects in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. NOTE: If a research repository from a previous study is used to identify subjects, there must be an IRB approved HIPAA waiver for this activity in the new protocol.

(1) Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research.
(2) If a contractor makes the initial contact by letter, the VA investigator must sign the letter.

NOTE: This paragraph does not apply to situations where a Veteran calls in response to an advertisement.

(3) If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing (e.g., by use of a delegation letter) to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects, and about the ethical basis of the informed consent process and protocol.
(a) If the investigator contracts with a firm, e.g., a survey research firm, to obtain consent from subjects, collect private individually identifiable information from human subjects, or are involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the PO must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.
(b) The investigator must ensure that all original signed and dated informed consent documents are maintained in the investigator's research files, readily retrievable, and secure.

e. Reporting. The investigator is responsible for reporting unanticipated problems involving risks to subjects or others, serious unanticipated problems involving risks to subjects or others, local unanticipated serious adverse events, apparent serious or continuing noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research, including: any inappropriate access, loss, or theft of PHI; noncompliant storage,

transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI, in accordance with local facility or IRB SOPs and VHA Handbook 1058.01. NOTE: Current guidance on such reporting can be found on the ORO Web site at: http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/Memoranda%20and%20Clarifications/Forms/AllItems.aspx. This is an internal VA Web site not available to the public.

f. Research Records. All written information given to subjects must be in the investigator's research file along with the consent form(s). The investigator's research records are not yet scheduled in VHA RCS 10-1 and therefore must be retained until disposition instructions, as approved by NARA, are published in VHA RCS 10-1. NOTE: Once the disposition schedule is determined, records should be disposed in accordance with VHA RCS 10-

g. If the investigator leaves VA, all research records must be retained by the VA facility where the research was conducted.

h. VHA Health Record. A VHA health record must be created or updated, and a progress note created, for all research subjects (Veterans or Non-Veterans) who are admitted to VA medical facilities as in-patients, treated as outpatients at VA medical facilities, or when research procedures or interventions are used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or nursing homes) (see VHA Handbook 1907.01). Informed consent documents are not required to be in the health record.

i. Investigational Drugs and Devices. The investigator must conduct VA human subjects research involving investigational drugs and devices in accordance with all applicable VA policies and other federal requirements including, but not limited to: this Handbook, VHA Handbook 1108.04, and applicable FDA regulations. The storage and security procedures for test articles used in research must be reviewed and approved by the IRB and follow all applicable federal rules.